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UNITED STATES PATENT APPLICATION

FOR

SPINAL DISC ANNULUS RECONSTRUCTION METHOD

AND SPINAL DISC ANNULUS STENT

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DESCRIPTION

SPINAL DISC ANNULUS RECONSTRUCTION METHOD AND SPINAL DISC ANNULUS STENT

Cross-Reference to a Related Application

[001] This application is a continuation-in-part of US Patent Application No. 09/947,078, filed September 5, 2001, which is a continuation of U.S. Patent Application No. 09/484,706, filed January 18, 2000, which claims the benefit of U.S. Provisional Application No. 60/160,710, filed October 20, 1999, the entire contents of each are incorporated herein by reference.

Field of the Invention

[002] The invention generally relates to a surgical method of intervertebral disc wall reconstruction. The invention also relates to an annular repair device, or stent, for annular disc repair. The effects of said reconstruction are restoration of disc wall integrity and reduction of the failure rate (3-21%) of a common surgical procedure (disc fragment removal or discectomy). This surgical procedure is performed about 390,000 times annually in the United States.

Background of the Invention

[003] The spinal column is formed from a number of vertebrae, which in their normal state are separated from each other by cartilaginous intervertebral discs. The intervertebral disc acts in the spine as a crucial stabilizer, and as a mechanism for force distribution between the vertebral bodies. Without the disc, collapse of the intervertebral

space occurs in conjunction with abnormal joint mechanics and premature development of arthritic changes.

[004] The normal intervertebral disc has an outer ligamentous ring called the annulus surrounding the nucleus pulposus. The annulus binds the adjacent vertebrae together and is constituted of collagen fibers that are attached to the vertebrae and cross each other so that half of the individual fibers will tighten as the vertebrae are rotated in either direction, thus resisting twisting or torsional motion. The nucleus pulposus is constituted of loose tissue, having about 85% water content, which moves about during bending from ftont to back and from side to side,

[005] The aging process contributes to gradual changes in the intervertebral discs. The annulus loses much of its flexibility and resilience, becoming more dense and solid in composition. The aging annulus is also marked by the appearance on propagation of cracks or fissures in the annular wall. Similarly, the nucleus dessicates, increasing viscosity and thus losing its fluidity. In combination, these features of the aged intervertebral discs result in less dynamic stress distribution because of the more viscous nucleus pulposus, and less ability to withstand localized stresses by the annulus fibrosus due to its dessication, loss of flexibility and the presence of fissures. Occasionally fissures may form rents through the annular wall. In these instances, the nucleus pulposus is urged outwardly from the subannular space through a rent, often into the spinal column. Extruded nucleus pulposus can, and often does, mechanically press on the spinal cord or spinal nerve rootlet. This painful condition is clinically referred to as a ruptured or herniated disc.

[006] In the event of annulus rupture, the subannular nucleus pulposus migrates along the path of least resistance forcing the fissure to open further, allowing migration of the nucleus pulposus through the wall of the disc, with resultant nerve compression and leakage of chemicals of inflammation into the space around the adjacent nerve roots supplying the extremities, bladder, bowel and genitalia. The usual effect of nerve compression and inflammation is intolerable back or neck pain, radiating into the extremities, with accompanying numbness, weakness, and in late stages, paralysis and muscle atrophy, and/or bladder and bowel incontinence. Additionally, injury, disease or other degenerative disorders may cause one or more of the intervertebral discs to shrink, collapse, deteriorate or become displaced, herniated, or otherwise damaged and compromised.

[007] The surgical standard of care for treatment of herniated, displaced or ruptured intervertebral discs is fragment removal and nerve decompression without a requirement to reconstruct the annular wall. While results are currently acceptable, they are not optimal. Various authors report 3.1- 21% recurrent disc herniation, representing a failure of the primary procedure and requiring re- operation for the same condition. An estimated 10% recurrence rate results in 39,000 re- operations in the United States each year.

[008] An additional method of relieving the symptoms is thermal annuloplasty, involving the heating of sub-annular zones in the non-herniated painful disc, seeking pain relief, but making no claim of reconstruction of the ruptured, discontinuous annulus wall.

[009] There is currently no known method of annulus reconstruction, either primarily or augmented with an annulus stent.

Brief Summary of the Invention

[010] The present invention provides methods and related materials for reconstruction of the disc wall in cases of displaced, herniated, ruptured, or otherwise damaged intervertebral discs. In accordance with the invention, an annulus stent is disclosed for repair of an intervertebral disc annulus, comprising a centralized hub section, said hub section comprising lateral extensions from the hub section.

[011] In an exemplary embodiment, one or more mild biodegradable surgical sutures are placed at about equal distances along the sides of a pathologic aperture in the ruptured disc wall (annulus) or along the sides of a surgical incision in the annular wall, which may be weakened or thinned.

[012] Sutures are then tied in such fashion as to draw together the sides of the aperture, effecting reapproximation or closure of the opening, to enhance natural healing and subsequent reconstruction by natural tissue (fibroblasts) crossing the now surgically narrowed gap in the disc annulus.

[013] A 25-30% reduction in the rate of recurrence of disc nucleus herniation through this aperture has been achieved using this method.

[014] In another embodiment, the method can be augmented by creating a subannular barrier in and across the aperture by placement of a patch of human muscle fascia (the membrane covering the muscle) or any other autograft, allograft, or xenograft acting as a bridge or a scaffold, providing a platform for traverse of fibroblasts or other

normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture.

[015] A 30-50% reduction 'in the rate of recurrence of disc herniation has been achieved using the aforementioned fascial augmentation with this embodiment.

[016] Having demonstrated that human muscle fascia is adaptable for annular reconstruction, other blocompatible membranes can be employed as a bridge, stent, patch or barrier to subsequent migration of the disc nucleus through the aperture. Such biocompatible materials may be, for example, medical grade biocompatible fabrics, biodegradable polymeric sheets, or form fitting or non-form fitting fillers for the cavity created by removal of a portion of the disc nucleus pulposus in the course of the disc fragment removal or discectomy. The prosthetic material can be placed in and around the intervertebral space, created by removal of the degenerated disc fragments.

[017] Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[018] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[019] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate illustrative embodiments of the invention and, together with the description, serve to explain the principles of the invention.

[020] **FIG. 1** shows a perspective view of an illustrative embodiment of an annulus stent.

[021] **FIG. 2** shows a front view of the annulus stent of FIG. 1.

[022] **FIG. 3** shows a side view of the annulus stent of FIG. 1.

[023] **FIGs. 4A-4C** show a front view of alternative illustrative embodiments of an annulus stent.

[024] **FIGs. 5A-5B** show the alternative embodiment of a further illustrative embodiment of an annulus stent.

[025] **FIGs. 6A-6B** show the alternative embodiment of a further illustrative embodiment of an annulus stent.

[026] **FIG. 7** shows a primary closure of an opening in the disc annulus.

[027] **FIGs. 8A-8B** show a primary closure with a stent.

[028] **FIG. 9** shows a method of suturing an annulus stent into the disc annulus, utilizing sub-annular fixation points.

[029] **FIGs. 10A-10B** show a further illustrative embodiment of an annulus stent with flexible bladder being expanded into the disc annulus.

[030] **FIGs. 11A-11D** show an annulus stent being inserted into the disc annulus.

[031] **FIGs. 12A- 12B** show an annulus stent with a flexible bladder being expanded.

[032] **FIG. 13** shows a perspective view of a further illustrative embodiment of an annulus stent.

[033] **FIG. 14** shows a first collapsed view of the annulus stent of FIG. 13.

[034] **FIG. 15** shows a second collapsed view of the annulus stent of FIG. 13.

[035] **FIGs. 16A-16C** show the annulus stent of FIG. 13 being inserted into the disc annulus.

[036] **FIGs. 17A-17C** show a method of inserting the annulus stent of FIG. 13 into the disc annulus.

[037] **FIGs. 18A-18B** show a further illustrative embodiment of an annulus stent with a flexible bladder.

[038] **FIGs. 19A-19B** show another illustrative embodiment of an annulus stent with a flexible bladder.

[039] **FIG. 20** shows an expanded annulus stent with barbs on the radial extensions.

[040] **FIG. 21** shows a still further illustrative embodiment of an annulus stent with a compressible core.

Detailed Description of the Invention

[041] Reference will now be made in detail to an illustrative embodiment of the invention, which appears in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[042] In one embodiment of the present invention, as shown in FIG. 7, a damaged annulus **42** is repaired by use of surgical sutures **40**. One or more surgical sutures **40** are placed at about equal distances along the sides of a pathologic aperture **44** in the annulus **42**. Reapproximation or closure of the aperture **44** is accomplished by tying the sutures **40** so that the sides of the aperture **44** are drawn together. The reapproximation or closure of the aperture **44** enhances the natural healing and subsequent reconstruction by the natural tissue (e.g., fibroblasts) crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable, but permanent non- biodegradable may be utilized.

[043] Additionally, to repair a weakened or thinned wall of a disc annulus **42**, a surgical incision is made along the weakened or thinned region of the annulus **42**, and one or more surgical sutures **40** can be placed at about equal distances laterally from the incision. Reapproximation or closure of the incision is accomplished by tying the sutures **40** so that the sides of the incision are drawn together. The reapproximation or closure of the incision enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable, but permanent non-biodegradable materials may be utilized.

[044] In an alternative embodiment, the method can be augmented by the placement of a patch of human muscle fascia or any other autograft, allograft or xenograft in and across the aperture **44**. The patch acts as a bridge in and across the aperture **44**,

providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus **42**, prior to closure of the aperture **44**.

[045] In a further embodiment, as shown in FIGs. 8A-B a biocompatible membrane can be employed as an annulus stent **10**, being placed in and across the aperture **44**. The annulus stent **10** acts as a bridge in and across the aperture **44**, providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus **42**, prior to closure of the aperture **44**.

[046] In an illustrative embodiment, as shown in FIGs. 1-3, the annulus stent **10** comprises a centralized vertical extension **12**, with an upper section **14** and a lower section **16**. The centralized vertical extension **12** can be trapezoid in shape through the width and may be from about 8mm - 12mm in length.

[047] Additionally, the upper section **14** of the centralized vertical extension **12** may be any number of different shapes, as shown in FIGs. 4A and 4B, with the sides of the upper section **14** being curved or with the upper section **14** being circular in shape. Furthermore, the annulus stent **10** may contain a recess between the upper section **14** and the lower section **16**, enabling the annulus stent **10** to form a compatible fit with the edges of the aperture **44**.

[048] The upper section **14** of the centralized vertical extension **12** can comprise a slot **18**, where the slot **18** forms an orifice through the upper section **14**. The slot **18** is positioned within the upper section **14** such that it traverses the upper section's **14** longitudinal axis. The slot **18** is of such a size and shape that sutures, tension bands,

staples or any other type of fixation device known in the art may be passed through, to affix the annulus stent **10** to the disc annulus **42**.

[049] In an alternative embodiment, the upper section **14** of the centralized vertical extension **12** may be perforated. The perforated upper section **14** contains a plurality of holes that traverse the longitudinal axis of upper section **14**. The perforations are of such a size and shape that sutures, tension bands, staples or any other type of fixation device known the art may be passed through, to affix the annulus stent 10 to the disc annulus **42**.

[050] The lower section **16** of the centralized vertical extension **12** can comprise a pair of lateral extensions, a left lateral extension **20** and a right lateral extension **22**. The lateral extensions **20** and **22** comprise an inside edge **24**, an outside edge **26**, an upper surface **28**, and a lower surface **30**. The lateral extensions **20** and **22** can have an essentially constant thickness throughout. The inside edge **24** is attached to and is about the same length as the lower section **16**. The outside edge **26** can be about 8mm-16mm in length. The inside edge **24** and the lower section **16** meet to form a horizontal plane, essentially perpendicular to the centralized vertical extension **12**. The upper surface **28** of the lateral extensions **20** and **22** can form an angle from about 0°-60° below the horizontal plane. The width of the annulus stent **10** may be from about 3mm-5mm.

[051] Additionally, the upper surface **28** of the lateral extensions **20** and **22** may be barbed for fixation to the inside surface of the disc annulus 42 and to resist expulsion through the aperture **44**.

[052] In an alternative embodiment, as shown in FIG. 4B, the lateral extensions **20** and **22** have a greater thickness at the inside edge **24** than at the outside edge **26**.

[053] In an illustrative embodiment, the annulus stent **10** is a solid unit, formed from one or more of the flexible resilient biocompatible or bioresorbable materials well know in the art.

[054] For example, the annulus stent **10** may be made from:

[055] A porous matrix or mesh of biocompatible and bioresorbable fibers acting as a scaffold to regenerate disc tissue and replace annulus fibrosus as disclosed in, for example, U, S. Patent Nos. 5,108,438 (Stone) and 5,258,043 (Stone), a strong network of Miert fibers intermingled with a bioresorbable (or bioabsorable) material which attracts tissue ingrowth as disclosed in, for example, U.S. Patent No, 4,904,260 (Ray et al.).

[056] a biodegradable substrate as disclosed in, for example, U.S. Patent No. 5,964,807 (Gan at al.); or

[057] an expandable polytetrafluoroethylene (ePTFE), as used for conventional vascular grafts, such as those sold by W.L. Gore and Associates, Inc. under the trademarks GORE-TEX and PRECLUDE, or by Impra, Inc. under the trademark IMPRA.

[058] Furthermore, the annulus, stent **10**, may contain hygroscopic material for a controlled limited expansion of the annulus stent **10** to fill the evacuated disc space cavity.

[059] Additionally, the annulus stent **10** may comprise materials to facilitate regeneration of disc tissue, such as bioactive silica-based materials that assist in regeneration of disc tissue as disclosed in U.S. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.

[060] In further embodiments, as shown in FIGs. 5AB-6AB, the left and right lateral extensions **20** and **22** join to form a solid pyramid or cone. Additionally, the left and right lateral extensions **20** and **22** may form a solid trapezoid, wedge, or bullet shape. The solid formation may be a solid biocompatible or bioresorbable flexible material, allowing the lateral extensions **20** and **22** to be compressed for insertion into aperture **44**, then to expand conforming to the shape of the annulus' **42** inner wall.

[061] Alternatively, a compressible core may be attached to the lower surface **30** of the lateral extensions **20** and **22**, forming a pyramid, cone, trapezoid, wedge, or bullet shape. The compressible core may be made from one of the biocompatible or bioresorbable resilient foams well known in the art. The core can also comprise a fluid-expandable membrane, e.g., a balloon. The compressible core allows the lateral extensions **20** and **22** to be compressed for insertion into aperture **44**, then to expand conforming to the shape of the annulus' **42** inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.

[062] In an illustrative method of use, as shown in FIGs. 11A-D, the lateral extensions **20** and **22** are compressed together for insertion into the aperture **44** of the disc annulus 42. The annulus stent **10** is then inserted into the aperture **44**, where the lateral extensions **20**, **22** expand. In an expanded configuration, the upper surface **28** can substantially conform to the contour of the inside surface of the disc annulus 42. The upper section **14** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **42**, using means well known in the art.

[063] In an alternative method, where the length of the aperture **44** is less than the length of the outside edge **26** of the annulus stent **10**, the annulus stent **10** can be inserted laterally into the aperture **44**. The lateral extensions **20** and **22** are compressed, and the annulus stent **10** can then be laterally inserted into the aperture **44**. The annulus stent **10** can then be rotated inside the disc annulus **42**, such that the upper section **14** can be held back through the aperture **44**. The lateral extensions **20** and **22** are then allowed to expand, with the upper surface **28** contouring to the inside surface of the disc annulus **42**. The upper section **14** can be positioned within, or proximate to, the aperture **44** in the subannular space such that the annulus stent **10** may be secured to the disc annulus, using means well known in the art.

[064] In an alternative method of securing the annulus stent **10** in the aperture **44**, as shown in FIG. 9, a first surgical screw **50** and second surgical screw **52**, with eyeholes **53** located at the top of the screws **50** and **52**, are opposingly inserted into the adjacent vertebrae **54** and **56** below the annulus stent **10**. After insertion of the annulus stent **10** into the aperture **44**, a suture **40** is passed down though the disc annulus **42**, adjacent to the aperture **44**, through the eye hole **53** on the first screw **50** then back up through the disc annulus **42** and through the orifice **18** on the annulus stent **10**. This is repeated for the second screw **52**, after which the suture **40** is secured. One or more surgical sutures **40** are placed at about equal distances along the sides of the aperture **44** in the disc annulus **42**. Reapproximation or closure of the aperture **44** is accomplished by tying the sutures **40** in such a fashion that the sides of the aperture **44** are drawn together. The

reapproximation or closure of the aperture **44** enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable but permanent non-biodegradable forms may be utilized. This method should decrease the strain on the disc annulus **42** adjacent to the aperture **44**, precluding the tearing of the sutures through the disc annulus **42**.

[065] It is anticipated that fibroblasts will engage the fibers of the polymer or fabric of the intervertebral disc stent **10**, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.

[066] In an additional embodiment, as shown in FIGs. 10A-B, a flexible bladder **60** is attached to the lower surface **30** of the annulus stent **10**. The flexible bladder **60** comprises an internal cavity **62** surrounded by a membrane **64**, where the membrane **64** is made from a thin flexible biocompatible material. The flexible bladder **60** is attached to the lower surface **30** of the annulus stent **10** in an unexpanded condition. The flexible bladder **60** is expanded by injecting a biocompatible fluid or expansive foam, as known in the art, into the internal cavity **62.** The exact size of the flexible bladder **60** can be varied for different individuals. The typical size of an adult nucleus is about 2 cm in the semi-minor axis, 4 cm in the semi-major axis, and 1.2 cm in thickness.

[067] In an alternative embodiment, the membrane **64** is made of a semi-permeable biocompatible material.

[068] In an illustrative embodiment, a hydrogel is injected into the internal cavity **62** of the flexible bladder **60**. A hydrogel is a substance formed when an organic polymer (natural or synthetic) is cross-linked via, covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice structure, which entraps water molecules to form a gel. The hydrogel may be used in either the hydrated or dehydrated form.

[069] In a method of use, where the annulus stent **10** has been inserted into the aperture **44**, as has been previously described and shown in FIGs. 12 A-B, an injection instrument, as known in the art, such as a syringe, is used to inject the biocompatible fluid or expansive foam into the internal cavity **62** of the flexible bladder **60**. The biocompatible fluid or expansive foam is injected through the annulus stent **10** into the internal cavity **62** of the flexible bladder **60**. Sufficient material is injected into the internal cavity **62** to expand the flexible bladder **60** to fill the void in the intervertebral disc cavity. The use of the flexible bladder **60** is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.

[070] The surgical repair of an intervertebral disc may require the removal of the entire disc nucleus, being replaced with an implant, or the removal of a portion of the disc nucleus thereby leaving a void in the intervertebral disc cavity. The flexible bladder **60** allows for the removal of only the damaged section of the disc nucleus, with the expanded flexible bladder **60** filling the resultant void in the intervertebral disc cavity. A major advantage of the annulus stent **10** with the flexible bladder **60** is that the incision area in

the annulus **42** can be reduced in size, as there is no need for the insertion of an implant into the intervertebral disc cavity.

[071] In an alternative method of use, a dehydrated hydrogel is injected into the internal cavity **62** of the flexible bladder **60**. Fluid, from the disc nucleus, passes through the semipermeable membrane **64** hydrating the dehydrated hydrogel. As the hydrogel absorbs the fluid the flexible bladder **60** expands, filling the void in the intervertebral disc cavity.

[072] In an alternative embodiment, as shown in FIG. 13, the annulus stent **10** is substantially umbrella shaped, having a central hub **66** with radially extending struts **67**. Each of the struts **67** is joined to the adjacent struts **67** by a webbing material **65**, forming a radial extension **76** about the central hub **66**. The radial extension **76** has an upper surface **68** and a lower surface **70**, where the upper surface **68** contours to the shape of the disc annulus' **42** inner wall. The radial extension **76** may be substantially circular, elliptical, or rectangular in shape. Additionally, as shown in FIG. 20, the upper surface **68** of the radial extension **76** may be barbed **82** for fixation to the disc annulus' **42** inner wall and to resist explusion through the aperture **42**.

[073] As shown in FIGs. 14 and 15, the struts **67** are formed from flexible material, allowing the radial extension **76** to be collapsed for insertion into aperture **44**, then to expand conforming to the shape of the inner wall of disc annulus **42**. In the collapsed position, the annulus stent **10** is substantially frustoconical or shuttlecock shaped, and having a first end **72**, comprising the central hub **66**, and a second end **74**.

[074] In an alternative embodiment, the radial extension **76** has a greater thickness at the central hub **66** edge than at the outside edge.

[075] In an embodiment, the annulus stent **10** is a solid unit, formed from one or more of the flexible resilient biocompatible or bioresorbable materials well known in the art.

[076] Additionally, the annulus stent **10** may comprise materials to facilitate regeneration of disc tissue, such as bioactive silica based materials that assist in regeneration of disc tissue as disclosed in U.S. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.

[077] Alternatively, as shown in FIG. 21, a compressible core **84** may be attached to the lower surface **70** of the radial extension **76**. The compressible core **84** may be made from one of the biocompatible or bioresorbable resilient foams well known in the art. The compressible core **84** allows the radial extension **76** to be compressed for insertion into aperture **44** then to expand conforming to the shape of the disc annulus' **42** inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.

[078] In an additional embodiment, as shown in FIG. 18A and 18B, a flexible bladder **80** is attached to the lower surface **70** of the annulus stent **10**. The flexible bladder **80** comprises an internal cavity **86** surrounded by a membrane **88**, where the membrane **88** is made from a thin flexible biocompatible material. The flexible bladder **86** is attached to the lower surface **70** of the annulus stent **10** in an unexpanded condition. The flexible bladder **80** is expanded by injecting a biocompatible fluid or expansive foam, as known in the art, into the internal cavity **86**. The exact size of the flexible bladder **80** can be varied

for different individuals. The typical size of an adult nucleus is 2 cm in the semi-minor axis, 4 cm in the semi-major axis and 1.2 cm in thickness.

[079] In an alternative embodiment, the membrane **88** is made of a semi-permeable biocompatible material.

[080] In a method of use, as shown in FIGs. 16A-16C, the radial extension **76** is collapsed together, for insertion into the aperture **44** of the disc annulus **42**. The radial extension **76** is folded such the upper surface **68** forms the inner surface of the cylinder. The annulus stent **10** is then inserted into the aperture **44**, inserting the leading end **72** though the aperture **44** until the entire annulus stent **10** is within the disc annulus **42.** The radial extension **76** is released, expanding within the disc **44.** The upper surface **68** of the annulus stent **10** contours to the inner wall of disc annulus **42**. The central hub **66** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **42** using means well known in the art.

[081] It is anticipated that fibroblasts will engage the fibers of the polymer of fabric of the annulus stent **10**, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.

[082] In an alternative method of use, as shown in FIGs. 17A-17C, the radial extension **76** is collapsed together for insertion into the aperture **44** of the disc annulus **42**. The radial extensions **76** are folded such that the upper surface **68** forms the outer surface of the stent, for example in a frustoconical configuration as illustrated. The annulus stent **10** is then inserted into the aperture **44**, inserting the tail end **74** through the aperture **44**

until the entire annulus stent **10** is in the disc. The radial extensions **76** are released, expanding within the disc. The upper surface **68** of the annulus stent **10** contours to the disc annulus' **42** inner wall. The central hub **66** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **42**, using means well known in the art.

[083] In an embodiment, the barbs **82** on the upper surface **68** of the radial extension **76** engage the disc annulus' **42** inner wall, holding the annulus stent **10** in position.

[084] In a method of use, as shown in FIGs. 12A-12B, where the annulus stent **10** has been inserted into the aperture **44**, as has been previously described. Similarly, for the stent shown in FIGs. 18 through 21, an injection instrument, as known in the art, such as a syringe, can be used to inject the biocompatible fluid or expansive foam into the internal cavity **86** of the flexible bladder **80**. The biocompatible fluid or expansive foam is injected through the annulus stent **10** into the internal cavity **86** of the flexible bladder **80**. Sufficient material is injected into the internal cavity **86** to expand the flexible bladder **80** to fill the void in the intervertebral disc cavity. The use of the flexible bladder **80** is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.

[085] All patents referred to or cited herein are incorporated by reference in their entirety to the extent they are not inconsistent with the explicit teachings of this specification, including; U.S. Patent No. 5,108,438 (Stone), U.S. Patent No. 5,258,043 (Stone), U.S. Patent No. 4,904,260 (Ray et al.), U.S. Patent No. 5,964,807 (Gan et al.),

U.S. Patent No. 5,849,331 (Ducheyne et al.), U.S. Patent No. 5,122,154 (Rhodes), U.S. Patent No. 5,204,106 (Schepers at al.), U.S. Patent No. 5,888,220 (Felt et al.) and U.S. Patent No. 5,376,120 (Sarver et al.).

[086] Various materials know to those skilled in the art can be employed in practicing the present invention. By means of example only, the body portions of the stent could be made of NiTi alloy, plastics including polypropylene, polyethylene, stainless steel and other biocompatible metals, chromium cobalt alloy, or collagen. Webbing materials can include silicone, collagen, ePTFE, DACRON, polyester, polypropylene, polyethylene, and other biocompatible materials and can be woven or non-woven. Membranes might be fashioned of silicone, propylene, polyester, SURLYN, PEBAX, polyethylene, polyurethane or other biocompatible materials. Inflation fluids for membranes can include gases, liquids, foams, emulsions, and can be or contain bioactive materials. The stent body, webbing and/or membrane can be drug eluting or bioresorbable, as known in the medical implant arts.

[087] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.